



120 W. Commercial Avenue, Moonachie, NJ 07074 201-939-0716 800-888-0908 Fax: 201-939-4503

510(k) Summary
BioArterial Plus Arterial Blood Flow Enhancement System
510(k) Number K072666

Submitted in accordance with the requirements of SDMA 1990 and 21CFR807.92.

1. APPLICANT'S INFORMATION:

May - 5 2007

Ron Motherwell
Executive Vice President
PH: 201 939-0716
FX: 201 939-4503
Internet: <http://www.biocompression.com>
Medical Establishment
Registration No.: 2424387

2. SUBMITTER'S INFORMATION

James Jochen Rogers
General Manager
Coastal Consulting Group, Ltd.
P.O. Box 470218
Broadview Heights, OH 44141
PH/FX: 440 546.4936
Mobile: 724 713.2298
E-mail: coastalcg@earthlink.net
Internet: <http://www.coastalcg.com>

3. Date: May 18, 2007

4. DEVICE INFORMATION

DEVICE NAME: BioArterial Plus Arterial Blood Flow Enhancement System
Classification Panel: Cardiovascular and Respiratory Devices
Classification Number: 870.5800
Product Nomenclature: Compressible Limb Sleeve
Product Code(s): JOW
Trade/Proprietary Name: BioArterial Plus Arterial Blood Flow Enhancement System
Common Name: BioArterial Plus Arterial Blood Flow Enhancement System
510(k) Submission Type: Traditional
Request for Confidentiality under 21CFR §807.95: NO

5. DEVICE CLASSIFICATION:

Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular Devices.

6. PREDICATE DEVICE(s):

- K061857 Model IC-1545-KT/-F Intermittent Circulator
- K942530 ACI Medical Art-Assist Model AA-1000
- K914461/K951683/K953648 Novamedix AV Impulse

7. DEVICE DESCRIPTION:

The BioArterial Plus Arterial Blood Flow Enhancement System is intended for the improvement of blood circulation in the lower extremities to help prevent and reduce complications of poor circulation, by increasing arterial blood flow through the application of bilateral or unilateral intermittent compression to the foot and calf.

The AC-powered device for consists of a pump, inflatable garments, and interconnection tubing. In operation, the device is attached via interconnect tubing to sleeves or garments containing discrete inflatable chambers applied externally and bilaterally over the feet and calves. Unique connector fittings on the interconnect tubing prevent accidental and incorrect pump/garment/anatomy combinations. Garments are available in a unique anatomical configuration, providing a single inflation chamber for the foot, and a single inflation chamber for the calf. Garments are supplied non-sterile, intended for single patient use, and are intended to be applied over bandages or clean hosiery. Hook-and-loop fasteners support a wide range of anatomy sizes. The device is intended for home use.

8. INDICATIONS FOR USE:

The BioArterial Plus Arterial Blood Flow Enhancement System is intended as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes:

- Amputations (minor)
- Angioplasty / stent failure
- Arteriopathic wounds
- Graft failure
- Intermittent claudication
- Ischemia
- Night pain
- Rest pain
- Small vessel disease
- Ulcers

9. TECHNOLOGICAL CHARACTERISTICS:

The manufacturer believes that the technological characteristics of the BioArterial Plus Arterial Blood Flow Enhancement System are substantially similar to those of the predicate devices.

10. PERFORMANCE DATA:

Performance testing was performed and assures that the product meets its specifications.

Bench testing was performed, comparing the inflation cycle profiles of the product to the predicate devices. The results of the testing demonstrate similar risetimes (time required to reach pressure), cycle times (total inflated and deflated times within a cycle), and inflation pressures.

11. STATEMENT OF SUBSTANTIAL EQUIVALENCE:

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices in terms of features, functionality, and bench comparison testing, the manufacturer believes that the BioArterial Plus Arterial Blood Flow Enhancement System is substantially equivalent to the predicate devices, and does not raise any new questions of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2007

Bio Compression Systems, Inc.
c/o Mr. Jay Y. Kogoma
Intertek Testing Services NA, Inc.
2307 E Aurora Rd. Unit B7
Twinsburg, OH 44087

Re: K072666
BioArterial Plus, Arterial Blood Flow Enhancement System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: September 19, 2007
Received: September 21, 2007

Dear Mr. Kogoma:

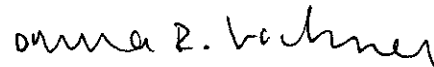
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K072666

Device Name: BioArterial Plus Arterial Blood Flow Enhancement System

Indications for Use:

The BioArterial Plus Arterial Blood Flow Enhancement System is intended as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes:

- Amputations (minor)
- Angioplasty / stent failure
- Arteriopathic wounds
- Graft failure
- Intermittent claudication
- Ischemia
- Night pain
- Rest pain
- Small vessel disease
- Ulcers

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley R. Lockner

(Signature-Off)

Cardiovascular Devices

Page 1 of 1

510(k) number K072666